

Full Text HD-96-007

## PEDIATRIC REHABILITATION

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### Keywords:

Pediatrics

Rehabilitation/Therapy, Physical

National Institute of Child Health and Human Development

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: July 24, 1996

Application Receipt Date: November 13, 1996

## PURPOSE

The National Institute of Child Health and Human Development (NICHD) invites applications for research project grants (R01) and First Independent Research Support And Transition (FIRST) Awards (R29) to conduct rehabilitation research to improve the management of the movement limitations of infants or children with physical disabilities due to injury, disease or disorders existing at birth. The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is interested in promoting research on the development of new and improved rehabilitation protocols for patients with juvenile rheumatoid arthritis. A primary purpose of this initiative is to encourage the development and evaluation of specific interventions to clinically evaluate, reduce or reverse the movement limitations of infants or children with physical disabilities. Another purpose is to understand the causes, consequences, and prevalence of movement limitations within defined populations.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Pediatric Rehabilitation, is related to the priority area of chronic and disabling conditions and the goal to reduce health disparities among Americans. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

#### ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Awards (R29). Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

#### MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) research project grant (R01) and FIRST award (R29) mechanism. The direct costs for the R01 may not exceed \$100,000 per year. The total project period for an R29 application submitted in response to the present RFA must be for five years. The total costs for the R29 will be determined by the guidelines currently in effect on the receipt date of the RFA. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The anticipated award date is July 1, 1997.

This RFA is a one-time solicitation. Future unsolicited continuation applications will compete with all unsolicited investigator-initiated applications and be reviewed according to the customary peer review procedures.

#### FUNDS AVAILABLE

Applications submitted in response to this RFA will compete for direct costs of approximately \$750,000 that have been made available for the first year of support for the program. It is expected that approximately six awards will be made by NICHD. The number of awards depends on the overall scientific merit of the applications, their relevance to the stated goals of this RFA,

and the availability of funds. The NIAMS estimated funding (total costs) available for the first year of support is \$250,000. Funding is contingent upon receipt of scientifically meritorious applications. The NIAMS expects to fund one award in the area of rehabilitation in juvenile arthritis.

## RESEARCH OBJECTIVES

### Background

Currently there are approximately 3.8 million individuals, 17 years old or younger, living with chronic physical impairments and disabilities in the United States. Movement impairments are characteristic of many infants and children with disabilities due to conditions such as cerebral palsy, metabolic disorders, burns, juvenile arthritis, AIDS, amputation, cancer, injury to the brain or spinal cord, spina bifida or muscular dystrophy. These conditions are managed by a variety of therapies including orthopaedic surgery, physiotherapeutic interventions, medication, and the provision of adaptive equipment such as prostheses, orthoses, and wheelchairs. The goals of therapy include assisting the infant or child to achieve a greater level of independent movement and optimizing functional capacity. Although these interventions are widely used, very little systematic information exists regarding their effectiveness, especially in terms of the longer term development of the individual. A need exists as well to develop and evaluate new approaches to the clinical assessment and treatment of these conditions.

Considerable variation exists among infants and children with movement limitations that reflects a) the type and origin of physical disability, b) responses to treatment, and c) the presence of concomitant conditions. Some of these individuals become grossly inactive, resulting in a downward spiral of unhealthy development. Understanding the causes, consequences and prevalence of mobility limitations in different populations of infants and children with disabilities will provide a scientific basis for their more effective clinical management.

### Scope

Applications must address one or both of the following research themes.

I. Development and evaluation of new or improved evaluation techniques or interventions relevant to the movement limitations of infants and children.

Illustrative of such research is examination of both shorter- and longer-term outcomes of defined interventions to improve the independence of infants and children with movement limitations. This could include the development and empirical validation of models linking diagnostic information (e. g., images or strength measurements), interventions (e.g., surgery, prosthetics, or physiotherapy) and outcomes (e.g., improved mobility or health).

The NIAMS is interested in research projects that focus on the development and testing of new and improved rehabilitation techniques for children with juvenile arthritis. Research projects that examine efficacy, cost-effectiveness and explore the mechanisms underlying clinically significant beneficial effects are encouraged.

II. Achievement of better knowledge of the causes, consequences and prevalence of mobility limitations in different populations of infants and children with physically disabling conditions.

Illustrative of such research are longitudinal studies of interactions among biological factors, psychosocial and personality attributes, developmental landmarks, changing health status, and kinds of interventions received.

## INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508- 14513) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 28, 1994.

Investigators also may obtain copies of the policy from the program staff or contact person listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

## LETTER OF INTENT

Prospective applicants are asked to submit, by July 24, 1996, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to:

Louis A. Quatrano, Ph.D.  
National Center for Medical Rehabilitation Research  
National Institute of Child Health and Human Development  
Building 6100, Room 2A03  
Bethesda, MD 20892  
Telephone: (301) 402-2242  
FAX: (301) 402-0832  
Email: [quatrano1@hd01.nichd.nih.gov](mailto:quatrano1@hd01.nichd.nih.gov)

## APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 5/95) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, e-mail [ASKNIH@odrockm1.od.nih.gov](mailto:ASKNIH@odrockm1.od.nih.gov); and from the program administrator listed under INQUIRIES.

Applications for the FIRST award (R29) must include at least three sealed reference letters attached to the face page of the original application. FIRST award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The RFA label available in the PHS 398 (rev. 5/95) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies, in one package to:

DIVISION OF RESEARCH GRANTS  
NATIONAL INSTITUTES OF HEALTH  
6701 ROCKLEDGE DRIVE, ROOM 1040- MSC 7710  
BETHESDA, MD 20892-7710  
BETHESDA, MD 20817 (for express/courier services)

At the time of submission, two additional copies of the application must be sent to:

Susan Streufert, Ph.D.  
Division of Scientific Review  
National Institute of Child Health and Human Development  
Building 6100, Room 5E03H  
6100 Executive Boulevard  
Bethesda, MD 20892-7510  
Rockville, MD 20852 (for express/courier service)

Applications must be received by November 13, 1996. If an application is received after that date, it will be returned to the applicant without review. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed.

This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

#### REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NICHD. Incomplete applications will be returned to the applicant without further consideration. If

the application is not responsive to the RFA, NICHD staff may contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NICHD in accordance with the review criteria stated below.

As part of the initial merit review, a process may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to the RFA. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the Principal Investigator and the official signing for the applicant organization will be notified. Principal Investigators of applications judged to be non-competitive will receive summary statements containing reviewers' comments.

#### Review Criteria

- o scientific, technical, or medical significance and originality of the proposed research;
- o appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
- o qualifications and research experience of the Principal Investigator and staff, particularly, but not exclusively, in the area of the proposed research;
- o availability of the resources necessary to perform the research;
- o appropriateness of the proposed budget and duration in relation to the proposed research;
- o adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

The initial review group will also examine the provisions for the protection of human and animal subjects and the safety of the research environment.

#### AWARD CRITERIA

Applications will be selected based on scientific merit of the proposal, the availability of funds, and program relevance.

## INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Louis A. Quatrano, Ph.D.  
National Center for Medical Rehabilitation Research  
National Institute of Child Health and Human Development  
Building 61E, Room 2A03  
Bethesda, MD 20892-7510  
Telephone: (301) 402-2242  
FAX: (301) 402-0832  
Email: [quatrano1@hd01.nichd.nih.gov](mailto:quatrano1@hd01.nichd.nih.gov)

Susana Serrate-Sztejn, M.D.  
Arthritis Branch  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Natcher Building, Room 5AS-37G  
45 Center Drive MSC 6500  
Telephone: (301) 594-5032  
FAX: (301) 480-4543  
Email: [szteins@ep.niams.nih.gov](mailto:szteins@ep.niams.nih.gov)

Direct inquiries regarding fiscal matters to:

Mary Ellen Colvin  
Grants Management Branch  
National Institute of Child Health and Human Development  
Building 61E, Room 8A017  
Bethesda, MD 20892-7510  
Telephone: (301) 493-1303  
FAX: (301) 402-0915



Email: colvinm@hd01.nichd.nih.gov

Sally Nichols

Grants Management Office

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natcher Building, Room 5AS-53

45 Center Drive MSC 6500

Bethesda, MD 20892-6500

Telephone: (301) 549-3535

FAX: (301) 480-5450

Email: Nicholss@ep.niams.nih.gov

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.929 Medical Rehabilitation Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non- use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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[Return to RFAs Index](#)

[Return to NIH Guide Main Index](#)